

CLAIMS

We claim:

1. In combination with a lateral flow analysis device of the type wherein a test strip having a sample application area, a test results zone, a control zone and optionally a reagent zone,
5 is provided for detecting an analyte by well known immunological or chemical techniques, the analyte suspected of being present in a liquid sample, wherein the analyte is a drug, a hormone, an antibody, an etiological agent, a bacterium, a virus, or a portion thereof, or an antibody specific for that drug, and wherein the analyte is indicative of an etiological or disease state, the improvement which comprises at least one detectable dye
10 indicator located in the control zone or optionally adjacent to the control zone and capable of being moved through said test strip by the capillary flow of an applied liquid sample, the movement of said at least one detectable dye indicator being indicative of the movement of at least a portion of the sample through the test result zone and optionally the completion of the assay.
- 15 2. The improvement of claim 1, wherein said control zone further comprises a second dye indicator, being not noticeably soluble in or movable by an applied liquid sample, and having a detectable color different from the color of said at least one detectable dye indicator and before the sample is applied to the device being undetectable when applied to the same location of said control zone as said at least one detectable dye indicator.
- 20 3. The improvement of claim 2, the downstream movement of said at least one detectable dye indicator making said second dye indicator detectable and producing an apparent color change in the control zone indicative of movement of at least a portion of the sample thorough the test result zone and optionally the completion of the assay.

4. The improvement of claim 1, wherein the test strip is bibulous.
5. The improvement of claim 1, wherein the test strip is nonbibulous.
6. An analytical test device for detecting an analyte suspected of being present in a sample, comprising:

- a. a test strip having a sample application area to which the sample is applied, wherein the applied sample moves by capillarity through said test strip;
- b. a results area on said test strip downstream of the sample application area;
- c. an analyte detection means;
- d. a control means; and
- e. optionally a reagent zone.

7. The test device of claim 6, said results area further comprising a test result zone and a control zone.
8. The device of claim 7, said test result zone further comprising a portion of said test strip where the test result can be detected or observed at the completion of the assay.
9. The device of claim 7, said control zone further comprising a portion of said test strip where a control result can be detected or observed, said control result indicating that at least a portion of the sample has moved through said test result zone and optionally the completion of the assay.
10. The device of claim 6, wherein said control means further comprises at least one control dye applied to or adjacent to said control zone, said at least one control dye being solulizable by the sample and movable through said test strip, the movement of said at least one control dye being indicative of at least a portion of the sample having moved through said test result zone and optionally the completion of the assay.

11. The device of claim 10, wherein said control means further comprises at least one additional dye said at least one additional dye not being substantially moveable in said test strip, and said at least one additional dye being applied to the same location of said control zone as said at least one control dye.

5 12. The test device of claim 11, the movement of said at least one control dye away from said at least one additional control dye resulting in an apparent change of color of said control means located in said control zone.

13. An analytical test device for detecting an analyte suspected of being present in an applied liquid sample, the device comprising:

- 10 a. a test strip having a control results zone and a test result zone;
- b. an analyte detection means; and
- c. a control detection means.

14. The test device of claim 13, said control detection means further comprising at least one detectable dye reagent applied to said test strip.

15 15. The test device of claim 14, said at least one detectable dye reagent being soluble in the applied liquid sample.

16. The test device of claim 15, wherein said at least one detectable dye reagent moves by capillarity through said test strip when reached by the applied liquid sample.

17. The test device of claim 15, wherein said capillary movement of said at least one
20 detectable dye reagent in, into or out of said control result zone indicates that at least a portion of the applied liquid sample has moved through said test result zone and optionally the completion of the assay.

18. The test device of claim 14, wherein said at least one detectable dye reagent can be

detected by visible, fluorescent, radiographic or instrumental means.

19. The test device of claim 14, wherein said control detection means further comprises an additional dye reagent being not substantially moveable by the sample and having a detectable color different from the color of said at least one dye reagent and said at least one detectable dye reagent covering up or optionally mixing with said second dye reagent, such that said second dye reagent is not detectable by the user prior to application of the sample.

20. The test device of claim 19, wherein said additional dye reagent is substantially immobilized in or on said test strip and does not observably move through or on said test strip when reached by the applied liquid sample.

21. The test device of claim 19, wherein movement of said at least one detectable dye reagent results in a detectable color change, said color change indicating that at least a portion of the applied sample has moved through said test result zone and optionally the completion of the assay.

22. A procedural control for lateral flow analytical test devices for detecting an analyte suspected of being present in a sample, the procedural control comprising:

- a. a test strip;
- b. a control zone; and
- c. a control detection means.

23. The procedural control of claim 22, said control detection means further comprising at least one dye reagent having a first color and being applied to said test strip.

24. The procedural control of claim 23, said at least one dye reagent being soluble in an applied liquid sample.

25. The procedural control of claim 23, wherein an applied sample dissolves said at least one dye reagent, causing said at least one dye reagent to move by capillarity through said test strip and within, into or out of said control zone and said movement of said at least one dye reagent being indicative of the movement of the applied sample through the portion of said test strip upstream from said control zone and optionally the conclusion of the test.

26. The procedural control of claim 25, said test strip having a test result zone upstream of said control zone, and wherein the capillary movement of said at least one dye reagent in, into or out of said control result zone indicates that at least a portion of the sample has moved through said test result zone and optionally the completion of the assay.

27. The procedural control of claim 23, wherein said detectable color of said at least one dye reagent is visibly or instrumentally detectable.

28. The procedural control of claim 23, further comprising an additional dye reagent having a detectable color different from the detectable color of said at least one dye reagent and said at least one dye reagent covering up or mixing with said second dye reagent such that said second dye reagent is not detectable to the user prior to application of the sample, wherein said at least one dye reagent and said additional dye reagent are applied to the same location of said control zone.

29. The procedural control of claim 28, wherein said additional dye reagent is not significantly soluble in the applied sample.

30. The procedural control of claim 28, wherein said additional dye reagent is substantially immobilized in or on said test strip and does not observably move through or on said test strip when contacted by said sample.

31. The procedural control of claim 28, wherein said at least one dye reagent is caused to move out of said control zone, wherein the movement of said at least one dye reagent out of said control zone indicates that at least a portion of said sample has moved through the portion of the test strip upstream of said control zone and optionally the completion of the assay.

32. An analytical lateral flow test device for detecting an analyte suspected of being present in a liquid sample having a test strip, and analyte detection means, a test result zone and a control means, the control means comprising:

a. a first dye indicator having a first color and a second dye indicator having a second color, said first and second dye indicators being applied to the same application location on the test strip and said applied first and second dye indicators appearing to the user as a color other than the color of said second dye indicator.

33. The control means of claim 32, said first dye indicator being soluble in an applied liquid sample and being capable of capillary movement through the test strip when said first dye indicator has been contacted by said applied liquid sample.

34. The control means of claim 32, said second dye indicator being insoluble in said applied liquid sample, and being substantially immobilized in or on the test strip

35. The control means of claim 32, wherein application of the liquid sample causes movement of said first dye indicator from said application location, resulting in said second dye indicator becoming detectable to the user, the increased detectability of said second dye indicator being indicating that the applied liquid sample has past through the portion of the test strip upstream from the application site of said control means and

optionally the completion of the assay.